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10/612,754	07/01/2003	Thomas W. Mower	14564.37.1	5557

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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01/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/612,754	Applicant(s) MOWER ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 13-19, 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 20 and 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, the Amendment and Applicant's Arguments/Remarks, all filed 10/22/08 is acknowledged.

Claims 1-29 are pending in this action. Claims 1, 5-8, 20 and 23-29 have been amended. Claims 13-19, 21 & 22 have previously been withdrawn. Claims 1-12, 20 and 23-29 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 October 2008 has been entered.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-8, 20 and 23-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of “unrefined” Luo Han Guo powder and the limitation of “refined” Luo Han Guo liquid extract as now presently recited introduce new matter into claims. Applicant references support for the amendment, for example, in paragraphs [0027] & [0032] of the specification. However, the referenced paragraphs while discussing extraction methods in liquid and powder Luo Han Guo, does not specifically provide for the terms ‘refined’ Luo Han Guo and ‘unrefined’ Luo Han Guo powder as now claimed. Hence, there is lack of support for the limitation based on the instant specification.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12, 20 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su *et al.* (U.S. Patent Publication No. 2002/0068102 A1) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755).

The instant invention is drawn to a dietary supplement comprising: noni fruit; unrefined Luo Han Guo powder in a range from about 0.001 percent to about 3 percent by weight of the dietary supplement to mask flavor and/or scent of the noni fruit; refined Luo Han Guo liquid extract; and water.

The instant invention is also drawn to a method for improving the taste and odor of noni-based dietary supplements, comprising: providing a noni fruit product; and mixing with the noni fruit product Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit; the Luo Han Guo including: unrefined powdered Luo Han Guo extract in a range from about 0.001 percent to about 3 percent by weight of the dietary supplement; and refined liquid Luo Han Guo extract; whereby the unrefined powdered Luo Han Guo extract provides a masking effect to cover the unpleasant tastes and/or odors of the noni and the refined liquid Luo Han Guo acts as a sweetener for the dietary supplement.

The instant invention is also drawn to a method of improving the taste and odor of a noni-based dietary supplement, while simultaneously prolonging the shelf life thereof, comprising: providing a noni-based fruit product; mixing with the noni fruit product: refined liquid Luo Han Guo extract in an effective amount to sweeten the supplement; unrefined powdered Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit, wherein the effective amount is in a range from about 0.001 percent to about 3 percent by weight of the dietary supplement; raspberry fruit concentrate; and blueberry fruit concentrate.

Su *et al.* ('102) teach a dietary supplement to reduce cellular damage within the human body, whereby the dietary supplement includes reconstituted *Morinda citrifolia* (noni) fruit juice. The dietary supplement may also include other natural juices, such as natural blueberry juice concentrate and/or another natural juice concentrate. In one implementation, where liquid is extracted from the fruit of *Morinda citrifolia* to create the dietary supplement, it is referred to as 'Tahitian Noni' (see Abstract); (page 1, ¶ 13); (pg. 3, ¶ 28).

Su et al. teach that when the *Morinda citrifolia* fruit is ripe or overripe, the fruit provides a foul odor and/or taste (pg. 2, ¶ 25).

To prepare the supplement, *Morinda citrifolia* juice and puree are typically blended in a homogeneous blend, after which they are mixed with other ingredients, such as flavorings, sweeteners, nutritional ingredients, botanicals, extracts, and/or colorings. For example, flavorings may include artificial and/or natural flavor or ingredients that contribute to palatability. Sweeteners taught include natural sugars, artificial and high-intensity sweeteners. Specific sweeteners taught include natural sugars derived from corn, sucralose, stevia, saccharin, etc. (pg. 3, ¶ 35).

Consumption amounts of the dietary supplement may include more than one ounce per day or less than one ounce per day (pg. 1, ¶ 15 – pg. 2 ¶ 15).

With regard to the instant 'method of improving taste and odor' of noni based dietary supplements, it is the position of the Examiner that the instant method would be considered *prima facie* obvious based on the disclosure and teachings of *Su et al.*, as *Su et al.* teach a noni-

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based (*Morinda citrifolia*) dietary supplement that comprises at least one of flavorings and sweeteners (see for instance, Claim 13).

While *Su et al.* do not explicitly teach the instant amounts of noni fruit, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In *re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the Examiner’s position that Applicants have not demonstrated any surprising or unexpected results that accrue from the claimed amounts of noni fruit. The prior art clearly recognizes and teaches formulations based on noni fruit, particularly, *Morinda citrifolia*, used in dietary supplement formulations.

Su et al. as discussed above, teach that *Morinda citrifolia* provides a foul odor and/or taste when ripe or overripe. *Su et al.* also teach that flavoring agents, sweetening agents and the like are added in the supplement to contribute to palatability.

Su et al. do not teach inclusion of Luo Han Guo and raspberry concentrate.

Fischer et al. ('965) teach beverage and sweetening compositions comprising Luo Han Guo. The Luo Han Guo is provided in serum, puree or juice form and is used as a sweetening ingredient in place of sugar (see reference column 1, line 25 – col. 2, line 46). The use of Luo Han Guo allows for good tasting, storage-stable beverages and can be used in beverages, such as fruit juices and fruit juice-containing beverages (col. 2, lines 29-35). Luo Han Guo provides for

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a reduced calorie, flavoring system that has acceptable mouth feel and taste characteristics, particularly, a beverage without off-flavors (col. 2, lines 47-62); (col. 12, lines 27-30).

The Luo Han Guo-containing sweet juices can be concentrated but are mostly used as a single strength juice or as a dry powder (col. 4, lines 20-40).

Luo Han Guo is preferably present at an amount of from 0.25 to 10% (col. 10, lines 27-36). See also Examples on cols. 16-19. This amount is an overlapping amount, which reads on the instantly claimed amount of from about 0.1% to about 3%, as in claim 2.

Flavoring agents that can be used include raspberry, blueberry and the like (col. 4, lines 4-19); (col. 11, lines 44-59). The flavoring agents are provided in amounts of from 0.01% to 3% by weight (col. 11, lines 26-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry flavorants as taught by Fischer *et al.* within the dietary supplement of Su *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Fischer *et al.* teach a high-intensity sweetener, Luo Han Guo and teach that it is used as a sweetening agent, useful for providing good taste, with acceptable mouth feel and taste characteristics and also teach that additional flavorants and juices include raspberry to make low calorie beverages. The expected result would be an improved, palatable, reduced-calorie dietary supplement formulation.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or

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manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

The teachings of Su *et al.* are discussed above. Su *et al.* teach that *Morinda citrifolia* provides a foul odor and/or taste when ripe or overripe. Su *et al.* also teach that flavoring agents, sweetening agents and the like are added in the supplement to contribute to palatability.

Su *et al.* do not teach inclusion of Luo Han Guo and raspberry concentrate.

Downton *et al.* ('755) teach a sweet juice composition comprising Luo Han Guo. The sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage (see reference column 2, lines 1-26); (col. 3, lines 3-15) and Examples at cols. 12-15. An objective is to also produce a fruit juice, which is lower in sugar and calories by blending the very sweet (Luo Han Guo) juice with other fruit juices (col. 2, lines 27-30). Other suitable fruit juices disclosed include raspberry fruit juices (col. 10, lines 30-50). The sweet juice has a pH of less than about 4.5 (claim 18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry juices as taught by Downton *et al.*

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within the dietary supplement of Su *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Downton *et al.* teach a natural sweetener, Luo Han Guo, whereby the sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage and also teach that additional fruit juices, such as raspberry are included in the Luo Han Guo juice to make low calorie (lower sugar) beverages. The expected result would be an enhanced, palatable, low-calorie dietary supplement formulation.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

While the references do not explicitly teach the recited ranges or amounts (about 0.001 to about 3% Luo Han Guo powder) as claimed in instant claims 1, 20 and 23-29, the reference nonetheless recognize the use of the same components in combination to yield the same results as desired by Applicant. Moreover, Applicant has not demonstrated any superior or unexpected results that accrue from the claimed amounts. The determination of suitable or effective amounts is within the level of one of ordinary skill in the art.

With regards to the amendment to claim 1, Applicants have provided a product-by-process claim. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

* * * * *

Claims 1-12, 20 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yegorova (U.S. Patent No. 6,387,370 B1) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755).

The instant invention is drawn to a dietary supplement comprising: noni fruit; unrefined Luo Han Guo powder in a range from about 0.001 percent to about 3 percent by weight of the dietary supplement to mask flavor and/or scent of the noni fruit; refined Luo Han Guo liquid extract; and water.

The instant invention is also drawn to a method for improving the taste and odor of noni-based dietary supplements, comprising: providing a noni fruit product; and mixing with the noni fruit product Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit; the Luo Han Guo including: unrefined powdered Luo Han Guo extract in a range from about 0.001 percent to about 3 percent by weight of the dietary supplement; and refined liquid Luo Han

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Guo extract; whereby the unrefined powdered Luo Han Guo extract provides a masking effect to cover the unpleasant tastes and/or odors of the noni and the refined liquid Luo Han Guo acts as a sweetener for the dietary supplement.

The instant invention is also drawn to a method of improving the taste and odor of a noni-based dietary supplement, while simultaneously prolonging the shelf life thereof, comprising: providing a noni-based fruit product; mixing with the noni fruit product: refined liquid Luo Han Guo extract in an effective amount to sweeten the supplement; unrefined powdered Luo Han Guo in an effective amount to mask flavor and/or scent of the noni fruit, wherein the effective amount is in a range from about 0.001 percent to about 3 percent by weight of the dietary supplement; raspberry fruit concentrate; and blueberry fruit concentrate.

Yegorova ('370) teaches dietary supplement compositions that include extracts of *Morinda citrifolia*, also called Noni juice, and blueberry extracts (see Abstract); (col. 5, lines 22-26); (col. 6, line 66 – col. 7, line 10).

The preparations may be in solid form, such as a capsule, powder or granule, or a tablet form. Alternatively, the compositions may be dispersed into a suitable liquid. The composition may also be administered orally, preferably two to three times daily (col. 5, lines 14-20); (col. 11, lines 46-56).

The composition may comprise *Morinda citrifolia* extract in an amount ranging from about 50 mg to about 150 mg and blueberry extract in an amount ranging from about 25 mg to about 75 mg (col. 4, lines 21-34); (col. 7, lines 35-42); (col. 8, lines 62-66).

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In a preferred embodiment, the compositions may comprise 100 mg of *Morinda citrifolia* extract obtained by extracting the *Morinda citrifolia* fruit with water (col. 8, lines 1-7).

According to Yegorova, compositions comprising blueberry extract have been used to retard the aging process, as blueberries comprise large amounts of antioxidants. Blueberries rank in the top five of an antioxidant assay called ORAC (oxygen radical absorbance capacity) (col. 7, lines 7-10); (col. 8, lines 31-66).

Example 1 at columns 12-13 demonstrates a composition that includes *Morinda citrifolia* (100 mg) and blueberry extract (50 mg).

While Yegorova does not explicitly teach the instantly claimed amounts of noni fruit, the Examiner points out that, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the Examiner’s position that Applicants have not demonstrated any surprising or unexpected results that accrue from the claimed amounts of noni fruit. The prior art clearly recognizes and teaches dietary formulations based on noni fruit, particularly, *Morinda citrifolia* in combination with antioxidant-containing blueberry extract.

Yegorova does not teach inclusion of Luo Han Guo and raspberry concentrate.

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Fischer *et al.* ('965) teach beverage and sweetening compositions comprising Luo Han Guo. The Luo Han Guo is provided in serum, puree or juice form and is used as a sweetening ingredient in place of sugar (see reference column 1, line 25 – col. 2, line 46). The use of Luo Han Guo allows for good tasting, storage-stable beverages and can be used in beverages, such as fruit juices and fruit juice-containing beverages (col. 2, lines 29-35). Luo Han Guo provides for a reduced calorie, flavoring system that has acceptable mouth feel and taste characteristics, particularly, a beverage without off-flavors (col. 2, lines 47-62); (col. 12, lines 27-30).

The Luo Han Guo-containing sweet juices can be concentrated but are mostly used as a single strength juice or as a dry powder (col. 4, lines 20-40).

Luo Han Guo is preferably present at an amount of from 0.25 to 10% (col. 10, lines 27-36). See also Examples on cols. 16-19. This amount is an overlapping amount, which reads on the instantly claimed amount of from about 0.1% to about 3%, as in claim 2.

Flavoring agents that can be used include raspberry, blueberry and the like (col. 4, lines 4-19); (col. 11, lines 44-59). The flavoring agents are provided in amounts of from 0.01% to 3% by weight (col. 11, lines 26-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry flavorants as taught by Fischer *et al.* within the dietary supplement of Yegorova. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Fischer *et al.* teach a high-intensity sweetener, Luo Han Guo and teach that it is used as a sweetening agent, useful for providing good taste, with acceptable mouth feel and taste characteristics and also teach that

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additional flavorants and juices include raspberry to make low calorie beverages. The expected result would be an improved, palatable, reduced-calorie dietary supplement formulation.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

The teachings of Yegorova are delineated above.

Yegorova do not teach Luo Han Guo and raspberry concentrate.

Downton *et al.* ('755) teach a sweet juice composition comprising Luo Han Guo. The sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage (see reference column 2, lines 1-26); (col. 3, lines 3-15) and Examples at cols. 12-15. An objective is to also produce a fruit juice, which is lower in sugar and calories by blending the very sweet (Luo Han Guo) juice with other fruit juices (col. 2, lines 27-30). Other suitable fruit juices disclosed include raspberry fruit juices (col. 10, lines 30-50). The sweet juice has a pH of less than about 4.5 (claim 18).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the Luo Han Guo and raspberry juices as taught by Downton *et al.* within the dietary supplement of Yegorova. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Downton *et al.* teach a natural sweetener, Luo Han Guo, whereby the sweet fruit juice and concentrate can be made from Luo Han Guo juice so that it does not contain objectionable off-flavors and does not reform substantial quantities of off-flavors during storage and also teach that additional fruit juices, such as raspberry are included in the Luo Han Guo juice to make low calorie (lower sugar) beverages. The expected result would be a low-calorie dietary supplement composition that offers improved taste and flavoring.

With regard to the instantly claimed extraction amounts of Luo Han Guo and/or ORAC values, it is the position of the Examiner that it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts and/or values through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Absent a showing of unexpected results that accrue from the instant amounts/values, the instant amounts/values would be determined by the normal optimization process by the skilled artisan.

While the references do not explicitly teach the recited ranges or amounts (about 0.001 to about 3% Luo Han Guo powder) as claimed in instant claims 1, 20 and 23-29, the reference nonetheless recognizes the use of the same components in combination to yield the same results as desired by Applicant. Moreover, Applicant has not demonstrated any superior or unexpected

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results that accrue from the claimed amounts. The determination of suitable or effective amounts is within the level of one of ordinary skill in the art.

With regards to the amendment to claim 1, Applicants have provided a product-by-process claim. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

* * * * *

Pertinent Art

Prior art not relied upon but deemed relevant by Examiner:

- **Xiong *et al.*** (U.S. Patent No. 6,299,925 B1):

Xiong *et al.* teach a green tea extract formulation comprising Noni fruit, obtained from *Morinda citrifolia* plant. The formulation also contains fruit extracts, such as blueberry and raspberry extract (see Abstract; col. 6, lines 61-65; col. 8, Example VII; and Claim 23).

- **Pushpangadan *et al.*** (U.S. Patent No. 7,014,872):

Pushpangadan *et al.* teach an herbal nutraceutical formulation comprising a plant product composition of *Momordica charantia* (see claims).

Response to Arguments

Applicant's arguments filed 10/22/08 have been fully considered but they are not persuasive.

35 U.S.C. §103(a) Rejections of claims 1-12, 20 and 23 over Su *et al.* (U.S. Patent Publication No. 2002/0068102 A1) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755) and Yegorova (U.S. Pat. No. 6,387,370) in view of Fischer *et al.* (U.S. Patent No. 5,433,965) OR Downton *et al.* (U.S. Patent No. 5,411,755):

Applicant argued, “The cited references neither teach nor suggest a dietary supplement that includes noni juice and a powder made from dried, unrefined Luo Han Guo. Nor do the cited references teach or suggest inclusion of unrefined powdered in the weight ranges recited.”

Applicant's arguments were not deemed persuasive. The reference teachings, in combination, suggest and teach the use of noni in combination with the dried powder of Luo Han Guo. While the references do not explicitly teach the recited ranges or amounts (about 0.001 to about 3% Luo Han Guo powder) as claimed herein, the reference nonetheless recognize the use of the same components in combination to yield the same results as desired by Applicant. Moreover, Applicant has not demonstrated any superior or unexpected results that accrue from the claimed amounts. The determination of suitable or effective amounts is within the level of one of ordinary skill in the art. The prior art would be capable of achieving beneficial results, when taken in combination, absent a showing of evidence to the contrary. The art amply teaches that the use of liquid as well as dried powdered forms is well-known in the art.

Applicant's argument that “both Fischer and Downton teach away from the use of powders made from unrefined Luo Han Guo and in large quantities is limited” was not convincing because the prior art merely suggests that the use of such (unrefined Luo Han Guo) is

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limited when used in high quantities but does not suggest or teach to completely avoid unrefined Luo Han Guo. Moreover, Applicants themselves state that the ‘liquid and powder forms of Luo Han Guo can be extracted once or more than once’ (specification-page 13- paragraph 0032). Furthermore, the instant claims do not exclude the possibility of the powder being the end product or result of a dried sweet juice that has been extracted, such as taught by Fischer.

Applicant argues that “unrefined powdered Luo Han Guo has properties that are separate and distinct from the refined liquid Luo Han Guo.”

This argument was not persuasive. Whilst the properties between liquid and unrefined powdered Luo Han Guo may vary, the properties desired by Applicant, such as powdered Luo Han Guo to mask the flavor and/or scent of the noni fruit and liquid Luo Han Guo to provide for a sweetening property, in any event, does not render the claims patentable. “[T]he discovery of a previously unappreciated property of a prior art composition, (or of a scientific explanation for the prior art’s functioning), does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Lastly, Applicant argued, “A person of ordinary skill in the art would not know that unrefined Luo Han Guo powder could be used to mask unpleasant flavor and/or smell of noni.”

This argument was not persuasive. Absent any evidence to the contrary, the prior art would also be sufficiently capable of providing for both the sweetening as well as the flavor and/or scent masking properties, as desired by Applicant, based on the inclusion of Luo Han Guo in nutritional or supplemental compositions.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

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